

ORPHEUS Workshop on clinical PhD

”Research at the bed side”

Krakow November 29-30 2013

KRAKOW POSITION PAPER 2013

After Helsinki consensus statement on PhD training in clinical research from 2007 and Consensus document -Orpheus PhD quality indicators for combined PhD – clinical specialization programs drafted in 2011. On the basis of the Martin Declaration from 2012 ORPHEUS has decided to organize ORPHEUS workshop held in Krakow was focused on problems of clinical PhD studies. The tilted of the workshop was „Research on the bedside“ . Three topics discussed at the workshop were discussed based on different presentations:

-Organization of PhD program by bedside for medical doctors, dental doctors and other healthcare professionals

- Type of clinical publications suitable for PhD thesis

- Multidisciplinary character of most clinical research: Who is the author of the thesis?; Who is the mentor?

Problems observed were:

-Differences between basic and clinical oriented research

- Relationship between hospitals and PhD programs which vary from country to country (from clinical hospitals being part of medical schools, to being independent of medical schools ,or having different activities among themselves regulated under common agreements). In Europe there is no institution like NIH in US (devoted to research only). Research hospitals or other medical research facilities are very rare in Europe. Contrary to that many university hospitals have high responsibility as health providers for sometimes for huge population (definition of university hospital requires further discussion). Such position sometimes does not allow flexibility that might be required for dedicated scientific research.

-Additionally process of medical specialty training, duration, theoretical knowledge and practical skills requirements are strictly regulated by national and international rules. Therefore it is sometimes difficult to combine time available for clinical practice and clinical research. In spite of difficulties having protected time for research would be highly desirable in order to achieve optimal and high standard research results. It would be also recommended to keep the clinical specialty and research within the same field.

-As a consequence of all this the clinical PhD is usually done as a part-time endeavour as clinical PhD program is combined with specialty training with different models:

Separate model : where PhD program (3 years) is done first or later after clinical specialisation.

Concurrent model : where at the same time candidate is working with the patients and doing research concurrently.

The third model has protected time during specialisation for research (sometimes as a part of a day up to longer period that can be devoted exclusively to research which is patient oriented but it is not in direct service of hospital treatments of the patients).

The fourth, undesirable but existing model is when PhD students are doing their research in overtime period.

Clinical research can result in types of publications which are not common in other fields, for example:

CASE REPORT might be an important part of professional communication. However, only sometimes case reports are really discovering something new that can be considered as scientific contribution. Such cases are usually published in high ranking journals. Assessment if the case report is scientific contribution or not can be done only by competent and independent peer review process. Because such process is often not easy to organize some universities take different positions from not accepting case reports at all to accepting them depending on IF of the journal where it is published. Obviously only recommendation is inclusion of competent and independent peer review by assessment committee.

META-ANALYSIS (including Cochrane reports) in clinical decision making comes close to the top of evidence based medicine. From such a standpoint addition of few even one large clinical research to meta-analysis could change clinical behaviour. However it is clear that the scientific value depends also on general rules for scientific research (originality, novelty etc). Assessment of scientific contribution can be done only by competent and independent peer review process by assessment committee. Because sometimes it is not easy to organize such assessment committees, some universities take different positions from not accepting meta-analysis at all, to accepting them depending on IF of the journal where the research is published. Obviously only recommendation is inclusion of competent and independent peer reviewers in assessment committee.

MULTY CENTRIC (AND MULTIAUTHORED) RESEARCH represent specific problems when we find several authors e.g. co-author who is in the middle in order of many co-authors (50 or more). Usually it can be assumed that first author(s) contributed to idea and design of the project. If the journal where the report is published lists contribution done by each author the decision might be easier. If not so, assessment committee can ask co-authors to produce such statement. The research in such multinational settings could be a good experience for PhD students.

Articles published in proceedings of a conference are not considered to be a part of PhD thesis.

- Multidisciplinary character of most clinical research: Who is the author of the thesis?; Who is the mentor?

Having a co supervision on a PhD thesis is recommended in the multidisciplinary research. One paper can be a part of one or more PhD thesis depending on the justification provided by analysis of each authors contribution by assessment committee.

Regarding ethical aspect of clinical research it should be remembered that apart from preventing scientific fraud as in any other research acknowledging of PhD students' contribution as well as the contribution of other experts and protection of patients' rights should be taken into consideration. Furthermore, all PhD thesis based on clinical research should have statement about conflict of interest.

*Annex informed consent form